

September 7, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No: 2004N-0264

Dear Sir or Madame:

A workshop was held at Penn State University to discuss and develop strategies to utilize animal tissue biomass as a fuel in industrial and utility boilers and in other industrial processes, and to brainstorm on the development of a national infrastructure that could utilize animal tissue biomass as fuel on both a routine and large-scale emergency basis.

We are submitting a summary of this workshop in response to the ANPR asking for comments on economic and environmental issues associated with the disposal of animal tissues.

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Animal Tissue Biomass Workshop

July 22, 2004

**The Energy Institute
Penn State University**

Purpose: Discuss and develop strategies to utilize animal tissue biomass as a fuel in industrial and utility boilers and in other industrial processes, and to brainstorm on the development of a national infrastructure that could utilize animal tissue biomass as fuel on both a routine and large-scale emergency basis.

Structure of the Workshop: The morning session consisted of presentations outlining the issue of carcass and tissue disposal. Overviews were also provided on the technology of energy generating boilers and sources of fuel for cement kilns. Participants were divided up among break out groups to discuss 3 different topics. Listed below are the questions posed to each of the groups as well as a summary of the discussion points. All participants reconvened to develop a list of future action items which can also be found below.

Future Action Items

- ?? Feasibility Study is needed – without this nothing can move forward. On the surface it appears that animal biomass could be utilized as a source of energy for power generating units. This study would be conducted on a research scale to generate data such as how the tissue, etc burns, emissions, equipment needed etc. It is estimated that this phase would cost \$100,000 and could be completed in a 6 month time frame.
- ?? Find possible sources of funding for the feasibility study. Recommendations included industry, government (DHS, DOE, USDA), university, etc.
- ?? Gather and analyze data generated in Europe – EU may have feasibility, emissions, safety data.
- ?? Determine how much risk reduction is needed – this needs to be done by government agencies. There was much discussion about the need to go from no regulations to such stringent regulations and absolutes that nothing gets accomplished.
- ?? Determine the risks vs benefits of the alternatives
- ?? Continue the dialogue
- ?? Explore various scenarios (see above Logistics)
- ?? Study to explore the business feasibility
- ?? Study needed to determine the total cost and problem of carcass disposal (pets, road kill, livestock and poultry, equine)

'Concept-to-Commercialization'

Questions posed to the group

1. What research and development is needed?
2. Define the process
3. What data is needed to support commercialization and environmental regulations?
4. What time frame is needed to accomplish this?
5. Funding? How much is needed and what are possible sources
6. Who can own this? Who can provide the momentum?
7. Volunteers – where can this be piloted?

Group Discussion

- 1) As in each session, there was discussion of economics/incentives for SRM/ATB disposal. These discussions were tabled to be brought up in the wrap-up session.
- 2) Processes for two scenarios need to be developed -- a) Day-to-day usage of ABT and b) for an emergency/catastrophic event
- 3) Testing is needed to demonstrate technical feasibility by evaluating system operability, emissions, and handle ability. This is needed so that various organizations, including boiler operators and government agencies, can 'kick-the-tires-. For cost reasons, this should be performed at the pilot scale but must also be done at the demonstration scale.
- 4) The probability of utilizing ATB in boilers in the near future is low. If FDA makes a rule decision in 90 days, cofiring won't be an option because there still needs to be proven to industry and government (see #2).
- 5) Develop protocol for detecting 'micro-organisms' in stack gases and ash. – Much discussion about this in wrap-up. If not being regulated at all now, is this approach overkill???
- 6) Along the same lines, there was discussion about determining destruction temperatures of TSE's/prions. However, the consensus in the wrap-session was that this was a low-priority issue (if it was even needed).

Logistics

Questions posed to the group

1. Where are the facilities (power generating and cement)?
2. Distribution of livestock and poultry
3. How would material be transported?
4. What is needed for preprocessing and how would this be accomplished?
5. What is needed for biosecurity?
6. How would the above differ on a day to day basis vs. emergency disease?
7. What government agencies would have jurisdiction?
8. Define the regulatory issues

- 1) Where are the facilities (power generating and cement)?

Power generating boilers (utility, bubbling bed (BB), circulating bed) – DOE can provide list for nation

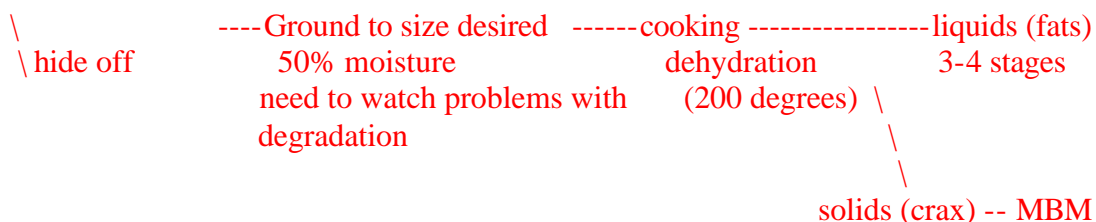
Cement kilns – 158 nationwide (only 2 states without) Lafarge can provide list

- 2) Distribution of livestock and poultry - USDA NASS/CEAH

- 3) What is needed for preprocessing and how would this be accomplished?

The process of carcasses or tissue

Cow ----- hide on



- a. raw material would have to be 1" x 0 for circulating beds and 2" x 0 for BB; moisture should not be a problem with the raw
- b. crax – 1-3% moisture – this should handle and burn well
- c. MBM – may be too dry and may not move through equipment well in winter

The opinion of the group was that bringing the material to the crax stage may be the best to logistically use this system.

- 4) How would material be transported? – If utilized current rendering infrastructure this is already in place. Renderers must be in compliance with all transportation regulations and requirements. Also, current system would cover 90% of country.
- 5) What is needed for biosecurity? If utilize existing infrastructure this is already in place.
- 6) How would the above differ on a day to day basis vs. emergency disease? If the system were in place for day – to –day , this would cover emergencies. May not be feasible to use for emergencies if an infrastructure and equipment were not in place. The capital investment is significant.
- 7) What government agencies would have jurisdiction? And define the regulatory issues

USDA - would have authority over disposal to prevent the spread of foreign animal diseases or diseases for which there are control programs.

FDA - has authority over what is included in animal feed, hence could prevent certain types of tissue or carcasses from being included in animal feed.

EPA - has authority over solid waste, water (run off) and air (if method of disposal may pollute or contaminate)

DOE - if disposed of by an energy generating entity may have some authority

DOT - has authority if material shipped in interstate commerce

OSHA- worker safety at plants

State and local equivalents of above may have more or less authority based on applicable laws

- 8) Investment bankers and backers have an interest in this

Economics and Incentives

Questions posed to the group

1. What is the value:
 - ?? fats/oils
 - ?? raw solids
 - ?? processed solids
2. What would it take to use these materials as fuel source:
 - ?? Tax incentives?
 - ?? Cheaper source of fuel?
 - ?? Emissions?
 - ?? Satisfy renewable energy standards?
3. How can incentives be generated?
4. Will this help improve air quality?
5. What is the value of a pre-existing infrastructure to deal animal health emergencies?

1) Value of ATB as a fuel would be \$1 - \$1.25/MMBTU - same as other waste fuels. This assumes little to no additional costs for handling/processing systems, permitting and a willing energy operator.

2) Government (USDA) would not fund infrastructure development alone based on emergency needs. Possible public/private partnership based on incentives desired for their involvement.

3) Potential supply volume, both regional and national, provides miniscule BTU's to the energy sector. 5 trillion BTU's is not much. Vibe from the energy sector was "why would we mess with this stuff for such little volume". However, if made easy (handling, regulatory, etc.) individual operators may consider.

4) With regards to disposal of dead stock, one participant felt that disposal needed to be mandated by government. Development of disposal options would then be driven by economics.

5) Incentives need to be developed for:

- Farmer/producer to send deads & downers for proper disposal.
- Renderer to continue pickup of deads/downers and to process SRMs.
- Boiler/Cement operator to burn ATB's.

6) A debate occurred over the need to render first due to the fact that generally the rendered fat is worth more than a fuel, especially a low value fuel. However, a renderer estimated that under a disposal rendering scenario, the cost to pick up a dead cow from a farm would

average \$150. This is on average \$100 more than the current charge. Assuming MBM yield from a dead cow is 200 pounds and that the long-term average MBM market is \$200/ton, only \$20 of this higher charge can be accounted for in lost MBM value. An explanation to cover the additional \$80 increase was not provided.

7) Permitting, not in my backyard (NIMBY) and handling issues are critical.